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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/640,211 | 08/16/2000 | Marion Wood | 11000.1021clu | 3582 |

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EXAMINER

TUNG, JOYCE

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1637

DATE MAILED: 11/07/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/640,211

Applicant(s)

WOOD ET AL.

Examiner

Joyce Tung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 1,3,4,7 and 17-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,5,6,8-16 and 31-34 is/are rejected.
- 7) ☒ Claim(s) 33 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Detailed Action.

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DETAILED ACTION

Election/Restriction

1. Applicant's election without traverse of claims 2, 5-6, 8-16 and 31-34 in Paper No. 9 is acknowledged. Since the response does not argue the restriction requirement made, the election is considered to be the election without traverse.
2. Claims 17-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected groups II and IV-VII, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

Specification

3. The title of the invention is not descriptive because the old title is directed to composition and method for the modification of gene transcription, while the claim language is directed to an isolated polynucleotide comprising SEQ ID NO: 2076 and encoding polypeptide SEQ ID NO: 2346 and 2347. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

4. Claim 33 is objected to because of the following informalities: in claim 33, SEQ ID NO: 1076 is an amino acid sequence, while claim 33 is claiming an isolated polynucleotide

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comprising a sequence selected from the group as listed in claim 33. The language is conflicting. It might be typographic error. Appropriate correction is required.

Information Disclosure Statement

5. The references AR (PCT international search report), AS-AV, BR-BV, CR-CV and DR-DS (GenBank data base) lined through were not considered, because the international search report and GenBank data base are not required to be listed on PTO-1449.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 2, 5-6, 8-16 and 31-34 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to the isolated polynucleotides consisting of SEQ ID. NO: 2076. It would require undue experimentation to make and use the claimed oligonucleotide. See M.P.E.P. §§ 706.03(n) and 706.03(z).

In Ex parte Forman, 230 USPQ 546 (Bd. App. 1986) the board considered the issue of enablement in molecular biology. The Board summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the

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invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, results of experiments in molecular biology are unpredictable.

To begin, there is no direction or guidance presented as regards the sequence of oligonucleotides claimed beyond the sequences disclosed as SEQ ID. No 2076. While the relative skill in the art is very high (the Ph.D. degree with laboratory experience), there is no predictability as to which sequences can be added to the oligonucleotide, and said oligonucleotide remain functional. The addition of sequences may allow for nonspecific interactions which would invalidate any assay, cause the formation of stem loops or other undesirable secondary structure, or interfere with hybridization to the template. Without providing the sequence for which protection is desired an infinite number of nucleotide sequences will have to be prepared and tested before they can be used in experiments.

As regards the nature of the invention, the claimed invention is drawn to polynucleotides. Polynucleotides are chemical compounds with an exact nucleotide sequence and claims drawn to polynucleotides should clearly define the nucleotide sequence for which protection is desired. While the breadth of these claims includes any oligonucleotide which includes the specified SEQ ID NO within its sequence, the specification lacks guidance on what additional sequences are to be added to the stated oligo.

The specification does provides working examples in which the determined cDNA is provided in SEQ ID NO: 2076 (See pg. 36, lines 1-3). There is some prior art (See column 6, lines 33-68 of Mullis, U.S. patent 4,683,202) for the selection of additional sequences, however not to the extent required by the open claim language "comprising." Accordingly, undue experimentation is required to make and use the invention as claimed. See M.P.E.P. §§ 706.03(n) and 706.03(z).

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8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9 Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 33 is vague and indefinite because of the language "degeneratively equivalent to SEQ ID NO: 2076". It is unclear what is meant by the language.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 2 and 31-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Uimari et al. (The Plant J. 1997, Vol. 12(6), pg. 1273-1284).

Uimari et al. disclose that plant Myb protein represents a group of transcription factors, and a fragment representing a flower bud-expressed gene, designated *myb26* was recovered and a full length cDNA was isolated from a pea flower bud cDNA library. The predicted protein is 217

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amino acids long (See the abstract). In this study, PCR with degenerate primers were used to analyze the presence of *myb*-like gene (See the Abstract).

Based upon the nucleic acid search report, the DNA sequence encoding Myb protein disclosed by Uimari et al. comprises SEQ ID NO: 2076, and comprises a sequence selected from the group as listed in claims 32-34 (See the attached nucleic acid search report). Thus, the teachings of Uimari et al. anticipate the limitations of claims 2 and 31-34.

12. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

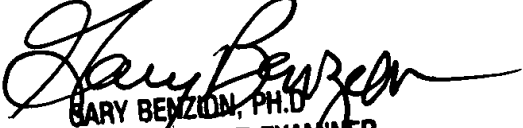
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

October 18, 2002


GARY BENZION, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600